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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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08/921,430 08/29/97 STEWART

EXAMINER
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BM41/1106

LAWRENCE N GINSBERG  
907 CITRUS PLACE  
NEWPORT BEACH CA 92660-3227

ART UNIT	PAPER NUMBER
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DATE MAILED:

11/06/98

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 8/29/97
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire \_\_\_\_\_ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-28 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-28 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2
- ☐ Interview Summary, PTO-413
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

## **DETAILED ACTION**

### ***Claim Rejections - 35 U.S.C. § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-16, 20, 23, 24 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted element is some device for counting and keeping track of the sponges.

Claims 4, 7, 8, 11, 20, 23 24 and 27 lack proper support in the specification.

In claims 1 and 17, it is not clear how the sponge has information that is "unique" for at least one surgical procedure. If it is unique, then it is for only one.

### ***Claim Rejections - 35 U.S.C. § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1- are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenaghan (3,941,132).

Lenaghan discloses surgical sponges including indicia 32, indicator tabs may be colored either to identify the location of the sponge or to differentiate between different packages of sponges. The sponge may also include an identification number printed directly on the sponge. The identification tab may also be used in conjunction with a counter system to count the sponges upon removal from the body. (3:40-51) The connector can be brightly colored and may also be a wire.

Thus, the sponge includes an x-ray detectable element and the information is on and/or within the sponge. The counter system inherently includes a bar code system as they are generally known for tracking inventories and they are known in the art for keeping track of sponges, if it is not inherent then it would have been obvious to one of ordinary skill. With respect to claims 1 and 17, Lenaghan clearly teaches each element except that the "unique machine-readable information is unique for at least one surgical procedure." However, Lenaghan teaches that different sized sponges are used for different procedures and that the size of the sponge will depend on the procedure performed. He additionally teaches that different sponges in the package will have different numbers and the these sponges may additionally have identification numbers printed directly on the sponges and the tie identification tabs may be used with counter systems to count the sponges. (3:7-50)

Lenaghan discloses the claimed invention except for the machine readable information is unique for at least one surgical procedure, wherein the information is located on a substrate, wherein the machine readable information further includes human readable information, wherein the information is body fluid repellant, wherein the substrate is a thin film or formed of an inert material, wherein the information is bar code information, wherein the information is compressed symbology, wherein the information is on a substrate attached with adhesive, wherein the x-ray detectable element is barium sulfate, wherein the adhesive is a heat type adhesive, wherein the substrate is a biologically inert material. It would have been an obvious matter of design choice to select any of these features, since applicant has not disclosed that these features unexpectedly solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the system as disclosed by Lenaghan.

I must conclude that the machine readable information is unique for at least one surgical procedure, wherein the information is located on a substrate, wherein the machine readable information further includes human readable information, wherein the information is body fluid repellant, wherein the substrate is a thin film or formed of an inert material, wherein the information is bar code information, wherein the information is compressed symbology, wherein the information is on a substrate attached with adhesive, wherein the x-ray detectable element is barium sulfate, wherein the adhesive is a heat type adhesive and wherein the substrate is a biologically inert

material are merely a matter of engineering design choice, and thus do not serve to patentably distinguish the claimed invention over the prior art.

Applicant is also reminded that arguments toward the criticality of an element will generally be given little patentable weight. The basis for criticality should be pointed out in the specification or supplied by affidavit.

### ***Conclusion***

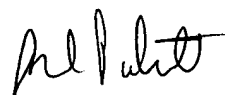
6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hardy (3,965,907) and Hirsch (4,477,256) cited by applicant disclose surgical sponges with barium sulfate. Nosek (5,031,642) discloses a surgical sponges and the use of bar codes on the packages to keep track of the sponges.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark O. Polutta whose telephone number is (703) 308-2114.

The examiner's supervisor, John Weiss, telephone number is (703) 308-2702. The fax phone number for official papers for this Group is (703) 305-3590. The fax phone number for unofficial papers for this Unit is (703) 306-4520.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0858.

Mark O. Polutta  
November 4, 1998



**MARK O. POLUTTA  
PRIMARY EXAMINER  
SECTOR 3700**